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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,983	07/21/2005	Horst G. Zerbe	AML/13131.19	7824

61114 7590 09/08/2010

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ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
09/08/2010	PAPER

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The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte HORST G. ZERBE and POMPILIA SZABO

Appeal 2010-005034
Application 10/542,983
Technology Center 1600

Before ERIC GRIMES, JEFFREY N. FREDMAN, and STEPHEN WALSH, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL[1]

This is an appeal under 35 U.S.C. § 134 involving claims to a multi-layer oral dosage form. The Examiner has rejected the claims as anticipated. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF THE CASE

Claim 1 is on appeal,[2] and reads as follows:

1. A multi-layer oral dosage form, comprising:

(a) a matrix core comprising a therapeutically effective amount of a first drug, wherein the matrix core allows sustained release of the first drug;

(b) a first layer, which is in contact with said matrix core, comprising a first portion of a pharmaceutically effective amount of a second drug, wherein the first layer allows sustained release of the second drug; and

(c) a second layer, which is also in contact with said matrix core, comprising a second portion of the second drug, wherein the second layer allows immediate release of the second drug.

Issue

The Examiner has rejected claim 1 under 35 U.S.C. § 102(b) as anticipated by Edgren.[3] The Examiner finds that Figure 3 of Edgren discloses the claimed multilayer oral dosage form (Answer 3). The Examiner finds that the claim's sustained release matrix core (a) corresponds to Edgren's element 13, the claim's first layer in contact with the matrix core (b) corresponds to Edgren's element 12, and the claim's second layer in contact with the matrix core (c) corresponds to Edgren's element 15 (*id.*).

Appellants contend that the Examiner erred in finding that Edgren discloses an oral dosage form having two sustained release layers because Edgren's "laminate layer 13 … does not allow 'sustained release of the first drug.' Instead laminate layer 13 of Edgren appears to be an instant release layer" (Appeal Br. 4).

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[2] Although claims 2-15, 17-19, 28, and 30 are reproduced in the Appeal Brief's Claims Appendix, they have been withdrawn from consideration by the Examiner (Office Action mailed Dec. 23, 2008, page 1).

[3] Edgren et al., US 4,946,685, issued Aug. 7, 1990

The issue presented is: Does the evidence of record support the Examiner's finding that Edgren discloses an oral dosage form having two sustained release layers?

Findings of Fact

1. Edgren discloses a "bilaminate dosage form … comprising a first lamina and a second lamina …, and wherein a drug is present in at least one of the lamina. An optional coat is disclosed that surrounds the bilaminate form" (Edgren, abstract).

2. Figure 3 of Edgren is shown below:

FIG. 3

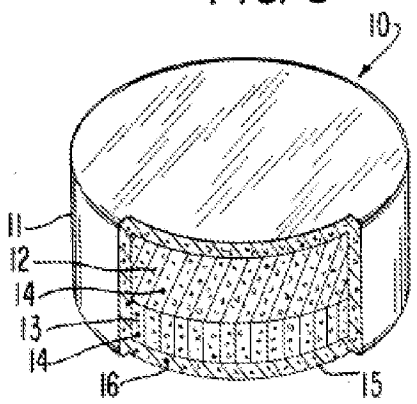

Figure 3 shows

> a dosage form 10 … in opened view and it comprises body 11, first lamina 12, a drug 14 in first lamina 12, second lamina 13 and a drug 14 in second lamina 13. Drug 14 present in first lamina 12 and in second lamina 13 may be the same or different. In FIG. 3, dosage form 10 additionally comprises an external coat 15. Coat 15 surrounds internal lamina 12 and internal lamina 13.

(*Id.* at col. 6, l. 55-63.)

3. Edgren discloses that "dosage form 10 comprises optional drug 16 in coat 15. The presence of drug 16 provides instant drug release when

dosage form 10 is introduced into an aqueous environment of use" (*id.* at col. 7, ll. 32-37).

4. Edgren discloses that

> the bilaminated structure of dosage form 10 comprises a fast drug releasing lamina 13, and a slower drug releasing lamina 12. The fast drug releasing lamina 13 begins to dispense drug 14 immediately for producing an initial plasma concentration of drug 14.... The slower drug releasing lamina 13 [sic, 12] releases drug 14 continuously and over time for producing a steady-state drug 14 concentration. The expression, "fast drug 14 releasing lamina 13 and slower drug 14 releasing lamina 12," as used for the purpose of this invention, denotes that lamina 13 releases drug 14 at a faster rate per unit time than does lamina 12.

(*Id.* at col. 14, ll. 54-67.)

5. Edgren discloses that one exemplary dosage form comprises

> (a) a drug delivery lamina comprising a cellulose ether composition means and a drug for continuously and slowly delivering the drug at a rate controlled by the lamina over an extended period up to 21 hours; and (b) a drug releasing lamina comprising a cellulosic ether composition means for delivering the drug immediately and over an unextended period up to 3 hours at a rate controlled by the lamina.

(*Id.* at col. 15, ll. 25-32.)

6. Appellants concede that Edgren's "[c]oat 15 may provide 'instant drug release' when a drug is included in the coat" (Appeal Br. 5).

7. Appellants do not point to any definition of "sustained release" in the Specification that requires drug release over a specific length of time.

Principles of Law

"[A]s an initial matter, the PTO applies to the verbiage of the proposed claims the broadest reasonable meaning of the words in their

ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the applicant's specification." *In re Morris*, 127 F.3d 1048, 1054 (Fed. Cir. 1997).

Analysis

Claim 1 is directed to a multi-layer oral dosage form comprising two sustained release portions (the matrix core and the first layer) and an immediate release layer (the second layer).

Appellants argue that Edgren's dosage form "includes two instant release layers and a sustained release layer" (Appeal Br. 6) rather than two sustained release layers and one instant release layer, as required by the claims (*id.*).

Appellants' arguments are not persuasive. Edgren's Example 31, which Appellants cite as disclosing that one of Edgren's two lamina layers is an instant release layer rather than a sustained release layer, describes the two lamina layers respectively as (i) "delivering the drug at a rate controlled by the lamina over an extended period up to 21 hours" and (ii) "delivering the drug immediately and over an unextended period up to 3 hours at a rate controlled by the lamina." The term "sustained release" is not defined in the Specification and, in accord with *In re Morris*, we give the term its broadest reasonable interpretation in view of the Specification. The broadest reasonable interpretation of "sustained release" reasonably encompasses release of a drug over the course of three hours, as specified for the fast release layer of Edgren. Appellants have not pointed to any disclosure in the

Specification that is inconsistent with this interpretation of the claim language.

Conclusion of Law

The evidence of record supports the Examiner's finding that Edgren discloses an oral dosage form having two sustained release layers.

SUMMARY

We affirm the rejection of claim 1 under 35 U.S.C. § 102(b).

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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